UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION **THIS DOCUMENT RELATES TO:** **All Direct Purchaser Actions**	**Case No. 1:15-cv-07488-CM-RWL**

PLAINTIFFS' OPPOSITION TO FOREST'S MOTION *IN LIMINE* NO. 14 PURPORTING TO PRECLUDE PLAINTIFFS FROM INTRODUCING EVIDENCE OF "RISING DRUG PRICING TRENDS" AND USING CERTAIN DESCRIPTIONS OF FOREST'S PATENT SETTLEMENT DEALS

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Forest's fourteenth *in limine* motion (ECF No. 795) wrongfully attempts to exclude evidence from governmental and peer-reviewed research studies about the impact of generic drug pricing by mischaracterizing it. The information contained in the cited studies is centrally-relevant evidence that is entirely appropriate for jury consideration and is not, in any way, unfairly prejudicial to Forest. Forest also improperly asks the Court to restrict Plaintiffs' ability to accurately describe defendants' misconduct to the jury. There is no basis for a blanket prohibition on the use of certain words, phrases, or descriptions in the abstract – especially when they precisely portray Forest's misconduct. The motion should be denied in its entirety.

I. GOVERNMENTAL AND PEER-REVIEWED RESEARCH ABOUT GENERIC DRUGS AND DRUG PRICES IS HIGHLY RELEVANT AND ADMISSIBLE.

In this antitrust case, Plaintiffs intend to show, *inter alia*, that Forest's interference with the entry of generic Namenda IR resulted in Plaintiffs paying higher prices for the brand name version of the drug. Evidence concerning the lower cost of generic drugs is clearly relevant to this inquiry. Forest attempts to mischaracterize evidence derived from various published research studies upon which Plaintiffs' experts rely that support a finding that generic drugs decrease drug prices as irrelevant and unduly prejudicial. Neither characterization is true. Forest is simply attempting to use a confused, backdoor method, to exclude proper, centrally relevant information, non-prejudicial information from reaching the jury.

A. Background: Admissibility of Research Studies Cited in the Motion

Forest's current motion does not challenge directly the underlying admissibility of the five research studies and articles it cites because those materials are plainly admissible at trial. Plaintiffs' experts have relied upon the cited research in forming their opinions, and the studies and articles in question constitute data that experts in the field would reasonable rely upon pursuant to Federal Rule of Evidence 703. The studies are also admissible as learned treatises

pursuant to Federal Rule of Evidence 803(18), and/or as public records pursuant to Federal Rule of Evidence 803(8).

Federal Rule of Evidence 703 provides that materials upon which an expert in the field rely may be disclosed to a jury "if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect." Additionally, on April 29, 2019 the parties in this case submitted a stipulation (ECF No. 693-A) providing that, consistent with Federal Rules of Evidence 703 and 705, a party's expert may rely on materials identified in his or her report(s) in providing his or her opinions notwithstanding the fact that the materials are not included on that party's exhibit list (the "Expert Reliance Stipulation").

Federal Rule of Evidence 803(18) specifically carves out a hearsay exception for "statement[s] contained in a treatise, periodical, or pamphlet, if . . . the statement is relied on by [an] expert on direct examination, and . . . the publication is established as a reliable authority by the expert's admission or testimony . . . or by judicial notice." And, Federal Rule of Evidence 803(8) provides a hearsay exception in a civil case for "factual findings from a legally authorized investigation" where "the opponent does not show the source of information or other circumstances indicate a lack of trustworthiness."

The five articles Forest cites in its motion are:

- Federal Trade Commission's January 2010 Staff Study, "*Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions,"* which plaintiffs have identified on their exhibit list (PX-1065) (the "FTC Staff Study") (Ex. 1 to Burke Decl.);

- Duane M. Kirking et al., *Economics and Structure of the Generic Pharmaceutical Industry*, 41 Am. Pharm. Ass'n 578, 580 (July/Aug. 2001) (Ex. 2 to Burke Decl.);

- Michael Allan et al., *Physician Awareness of Drug Cost: A Systematic Review*, 4 PLoS Med. 1486, 1486-1496 (Ex. 3 to Burke Decl.);

- C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77:3 Antitrust Journal, 947–89 (2011) (Ex. 4 to Burke Decl.); and

- Donald W. Logh & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, BioSocieties1, 2 (Mar. 2011) (Ex. 5 to Burke Decl.).

Plaintiffs have included the FTC Staff Study on their current exhibit list. Staff from the FTC's Bureau of Competition, Bureau of Economics, and Office of Policy Planning prepared the FTC Staff Study in accordance with their legal obligations as government employees. *See* FTC Staff Study, Ex. 1 to Burke Decl. at 7. The FTC Staff Study sets forth the methodology the FTC used to conduct the study, which was based on investigation and analysis of patent settlements filed with the FTC. *Id.* The Staff Study is admissible under FRE 703 as expert reliance material, under FRE 803 (8) as a public record, and under FRE 803 as a learned treatise. The remaining four articles are subject to the Expert Reliance Stipulation to the extent Plaintiffs' experts reasonably relied upon them. They are also subject to FRE 803(18)'s learned treatise research exception.

B. Research About the Impact of Generic Drug Entry Is Relevant and Admissible and Is Neither Unduly Prejudicial Nor Inflammatory.

Plaintiffs' expert economist Dr. Russell Lamb relied on an "extensive body of published research concerning the effects of generic competition in pharmaceutical markets." Amended Expert Report of Dr. Russell L. Lamb, dated Sept. 20, 2017 ("Lamb Rpt.") ¶ 67(a) (excerpt attached as Ex. 45 to the Declaration of Joseph Opper ("Opper Decl."). "These studies show that when AB-rated generic products enter the market, they typically do so at lower prices than their brand name counterparts and also capture a significant share of the total unit sales for the drug." *Id.* As a result, direct purchasers derive significant cost savings by switching to the lower price AB-rated generic product. *Id.*

Dr. Lamb specifically relies upon and cites the FTC Staff Study, which Plaintiffs have identified on their exhibit list (PX-1065). *See* Lamb Rpt. at ¶ 68(i). The FTC Staff Study analyzes and explains the impact of delayed generic entry as a result of reverse payment patent settlements on pharmaceutical prices. *See* FTC Staff Study, Ex. 1 to Burke Decl. at 1 ("'Pay-for delay" agreements are "win-win" for the companies: brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand's monopoly prices. Consumers lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices. For example, brand-name medication that costs $300 per month be sold as a generic for as little as $30 per month.").

Dr. Lamb cites the FTC Staff Study's conclusion that "a year after generic entry, with multiple generic competitors, generic prices were 85 percent below the pre-generic brand prices on average and 90 percent of prescriptions had switched from the brand to the generic." Lamb Rpt. at ¶ 72, citing FTC Staff Study, Ex. 1 to Burke Decl. at 8. Dr. Lamb also cites the Kirking article, *Economics and Structure of the Generic Pharmaceutical Industry*, a peer-reviewed study that found, among other things, that "generics are typically priced 30% to 60% less than their brand counterparts, with reductions of as much as 80% in some cases." Lamb Rpt. at ¶ 71, citing Kirking article, Ex. 2 to Burke Decl. at 580.

In its motion, Forest erroneously claims that Plaintiffs intend to introduce evidence that "blames pharmaceutical companies for the rising cost of pharmaceutical drugs or healthcare in general" and cites the FTC and Kirking studies as examples. Defs.' Br. at 1. Forest inappropriately labels these research studies as "inflammatory," when in fact these studies are, in fact, dispassionate, data-based analyses. *Id*. Forest also inaccurately implies that these studies contain evidence about "overall drug pricing trends," *id.* at 2, when these studies are focused on

the impact of generic drug prices on pharmaceutical markets. In this reverse payment antitrust case, evidence concerning the affordability of generic products, the high price of their branded counterparts, and how those price differentials affect pharmaceutical markets is relevant to proving antitrust liability, injury and damages. Forest's self-serving mischaracterization of the evidence cited in the studies has no basis in fact and provides no reason to exclude the research.

Forest also misrepresents the ruling in *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, No. CIV.A.05-CV-1887 DMC, 2009 U.S. Dist. LEXIS 103014 (D.N.J. Nov. 5, 2009) to the Court. In that patent infringement case, defendants sought to introduce evidence of (1) the price differential between brand-name and generic drugs; (2) the fact that the defendant manufactures generic drugs; (3) the underlying purposes of the Hatch-Waxman Act; and (4) the purported role that generic drugs will play in healthcare reform efforts. *Id*. at *12. Contrary to the implication in Forest's brief that evidence of the price differential between brand-name drugs and generic drugs was excluded, the court found just the opposite: "testimony concerning generic drugs and the Hatch-Waxman Act will likely aid in the jury understanding the context in which the case arises. . . . [t]herefore, such evidence is admissible." *Id*. at *13 The court precluded discussion only of the role of "generic drugs in the recent healthcare debate" as "entirely irrelevant" in that case which concerned patent infringement claims and not antitrust claims. *Id*.

C. Peer-Reviewed Research About Physician Awareness of Drug Costs Is Relevant and Admissible.

In his Expert Reply Report, Dr. Lamb cites the Allan study *Physician Awareness of Drug Cost: A Systematic Review*, which Forest also attempts to exclude without specifying any particular deficiencies in the study. *See* Amended Expert Report of Dr. Russell L. Lamb, dated Nov. 9, 2017 ("Lamb Reply.") ¶ 84, n.179 (excerpt attached as Ex. 6 to the Opper Decl.). The study shows that "physicians are largely unaware of the cost of pharmaceutical therapies, they do

not directly put pressure on prices through their decision making." *See* Lamb Reply ¶ 84, citing Allan, Ex. 3 to Burke Decl. at 1486-96. Dr. Lamb cited the Allan article to rebut Forest's experts' argument about Namenda prescribing patterns, and thus it is clearly relevant. Forest fails to cite anything prejudicial from the study.

D. Peer-Reviewed Research About Patent Litigation Statistics Is Relevant and Admissible.

Plaintiffs' patent litigation expert, George W. Johnston, Esq., cited the Hemphill & Lemley article *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, which discussed settlements between brand name and generic companies. *See* Expert Report of George W. Johnston ("Johnston Rpt.") (excerpt attached as Ex. 12 to the Opper Decl.) ¶ 104. The Hemphill article looked at data analyzing litigation success rates in pharmaceutical patent cases, and supports Mr. Johnston's analysis concerning the advice a reasonable and competent patent attorney would have provided the litigants at the time they settled the Namenda patent litigation about their likelihood of success in that litigation. It is in unclear from Forest's brief what fault it finds with the use of the article, as there is not even a parenthetical discussing it. In any event, there is no basis for a claim that research findings contained in this peer-reviewed journal article are, in any way, unduly prejudicial to Forest. *See generally* Pls.' Opp'n to Forest's Mot. i*n Limine* No. 2 Seeking to Exclude General Statistical Evidence of Outcomes in Unrelated Pharmaceutical Patent Litigations (explaining why statistical studies are highly probative and not unfairly prejudicial).

II. PLAINTIFFS' DESCRIPTIONS OF PATENT SETTLEMENTS SHOULD NOT BE CURTAILED IN THE ABSTRACT.

Plaintiffs are fully entitled to strike "hard blows" when describing Forest's misconduct. *United States v. Rude*, 88 F. 3d 1538, 1548 (9th Cir. 1996) ("the law permits the prosecution

considerable latitude to strike 'hard blows' based on the evidence and all reasonable inferences therefrom."); *United States v. Goichman*, 407 F. Supp. 980, 999 (E.D. Pa. 1976) *aff'd*, 547 F.2d 778 (3d Cir. 1976). Defendants seek to block the use of several terms from the trial. As one court observed, the "rich resources of the English language" should be available to litigants arguing their respective positions at trial; "[t]hat is a basic feature of our adversarial system, not an improper incitement to prejudice," and a court should be "disinclined to restrain the discretion of counsel in their choice of words in arguing their clients' cases, absent a showing of egregiously unfair prejudice arising out of that choice of words." *McEachron v. Glans.*, No. 98-CV-17, 1999 U.S. Dist. LEXIS 21926 at *13-14 (N.D.N.Y. Aug. 23, 1999).

A. Use of Certain Terms to Describe the Lexapro Amendment Is Appropriate.

Forest objects to Plaintiffs characterizing the deal Forest used to conceal its payment to Mylan to compensate Mylan for keeping its generic Namenda product off the market (the Lexapro Amendment) as a "payoff" – even though that is an accurate description of what that deal encompassed. The Lexapro Amendment allowed payments to flow from Forest to Mylan for the purpose of delaying generic competition. At trial, Plaintiffs are entitled to describe Forest's acts in a manner that "summarize[es] the central conduct" in which Forest engaged. *United States v. Felton*, 417 F.3d 97, 103 (1st Cir. 2005); *United States v. Shoff*, 151 F.3d 889, 893 (8th Cir. 1998) ("The prosecutor's opening was limited to describing what the government would attempt to prove. The use of colorful pejoratives is not improper."). The term "payoff" is an accurate description of Forest's conduct, Forest cannot complain that the term is pejorative – any uncomplimentary connotation results from Forest's acts, not Plaintiffs' phrasing. *See Felton*, 417 F.3d at 103 ("That the term is highly pejorative is true – but this is a function of the acts that the

defendants engaged in, not the government's inaccurate description of those acts.") (citation omitted).

Courts may, of course, prohibit the use of pejorative terms under Federal Rule of Evidence 403 "when such categorizations [are] inflammatory and unnecessary to prove a claim." *Aristocrat Leisure Ltd. v. Deutsche Bank Trust Co. Ams.*, No. 04 Civ. 10014(PKL), 2009 U.S. Dist. LEXIS 89183, at *19 (S.D.N.Y. Sept. 28, 2009); *see also A.I.A. Holdings, S.A. v. Lehman Bros.*, No. 97 Civ. 4978(LMM), 2002 U.S. Dist. LEXIS 22559, at *2-3 (S.D.N.Y. Nov. 21, 2002) (prohibiting use of the phrase "rat trading"). That is not the case here. Use of the term "pay-off" is not inflammatory but is purely descriptive. Likewise, the word is necessary as it is a term that precisely conveys what occurred. Courts have themselves used the term "payoff" to describe reverse payment agreements that delay generic competition. *See, e.g., In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 715 (N.D. Ill. Feb. 10, 2016 ("*FTC v. Actavis* decided whether it is illegal for a brand-name company to provide a payoff to a potential generic competitor to keep it from entering the market.").

Forest also asks this Court to preclude Plaintiffs from referring to the payments made to Mylan under the reverse payment Forest conveyed to Mylan using the payment term of the Lexapro Amendment by using the terms "bribe" or "bribery," words which plaintiffs do not presently intend to use before the jury. However, Plaintiffs object to a blanket prohibition on these words before the case even begins, as they are not inherently unfairly prejudicial or pejorative and may be appropriate depending on how the evidence in the case is presented. *See United States v. Woods*, No. 5:17-CR-50010, 2018 U.S. Dist. LEXIS 59308, at *2-5 (W.D. Ark. Apr. 3, 2018) (denying motion to exclude use of term "bribery" during trial). Neither of the cases Forest cites exclude the terms bribe or bribery. *See, e.g., Highland Capital Mgmt., L.P. v.*

Schneider, 551 F. Supp. 2d 173, 192-93 (S.D.N.Y. 2008) (prohibiting characterization of evidence as "inside information").

B. Use of the Terms "Anticompetitive" "Product of Conspiracy" "Illegal" or "Automatically Illegal" Is Appropriate to Describe the Earlier Patent Settlement Agreements.

Forest incorrectly describes the status of Forest's non-Mylan patent settlement agreements. Plaintiffs have not "abandoned" those facts or evidence. Although Plaintiffs are "not claiming that other patent litigation settlements between Forest and first filing generics were themselves unlawful under the *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) framework," Plaintiffs contend, as this Court stated, that "all of the other settlements to keep generic companies from competing that were signed before the Forest-Mylan settlement undergird and compound the anticompetitive effect of the Forest-Mylan deal." *See* ECF No. 565, Aug. 1, 2018 Letter from Bruce Gerstein to Judge McMahon at 1. Thus, these claims are nothing like those in the case Forest cites, *Catipovic v. Turley*, 68 F. Supp. 3d 983 (N.D. Iowa 2014) which prohibited the parties from referring to unpleaded claims as "fraud" "conspiracy" "collusion" or "breach" of any agreement. The *Catipovic* court also found that "the relevance and admissibility of any particular *evidence* of the conduct and relationship of the parties must be determined at trial." *Id.* at 999 (emphasis in original).

This Court, the U.S. Supreme Court in *Actavis*, and other federal courts, have determined that reverse payment patent settlements are "anticompetitive." *See* ECF No. 570 at 54 ("The fact remains, however, that the anticompetitive conduct at issue in this case is premised on the alleged barriers to entry put in place by Forest to prevent *all* generic competition, not just Mylan's."); *Actavis*, 570 U.S. at 154 ("But, one might ask, as a practical matter would the parties be able to enter into such an anticompetitive agreement?"); *In re Aggrenox Antitrust Litig.*, 94 F.

Supp. 224, 234 (D. Conn. 2015) ("Consumers who should enjoy competitive prices now will instead pay monopoly prices until the end term of the anticompetitive collusion"). Ignoring these decisions, Forests asks the Court to prevent Plaintiffs from doing the same thing -- describing the effects of the non-Mylan patent settlement agreements as "anticompetitive" or with similar adjectives. This the Court should not do.

Neither "anticompetitive" nor any of the other similar words Forest identifies are inherently unduly prejudicial or pejorative; they are simply accurate descriptions of the conduct that occurred. The Court should resist Forest's attempts to hamstring Plaintiffs from accurately portraying Forest's conduct by limiting the words used to characterize the patent settlements that preceded, informed, and set the stage for the Mylan reverse payment patent settlement.

III. CONCLUSION

Forest's Motion *in Limine* No. 14 should be denied.

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Respectfully Submitted:

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2019, I electronically filed the above by the CM/ECF system.

Respectfully submitted,

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